

1 REMARKS

2 Status of the Claims

3 Claims 1-51 are pending in the present application. Claims 29, 34, 35, and 45 have been amended
4 to more closely correlate the subject matter of the apparatus claims to the process claims. As described in
5 greater detail below, these amendments should enable the process claims to be examined along with the
6 elected claims (i.e., with Claims 1-28) of Group I.

7 Restriction Requirement

8 The Examiner indicates that there are three groups of patentably distinct inventions defined by
9 the claims of this application, as follows:

10 Group I is directed to a medical simulator and includes Claims 1-28.

11 Group II is directed to a method for making a medical simulator, including Claims 29-44.

12 Group III is directed to a method of using a medical simulator and includes Claims 45-51.

13 Status of Claim 28

14 The Examiner has indicated that Claim 28 is an apparatus claim that should be included in
15 Group I. However, Claim 28 recites a method for making an apparatus. Applicants respectfully
16 request clarification as to whether Claim 28 should be considered to be included within Groups I or
17 II.

18 Election:

19 In response to this Restriction, applicants hereby affirmatively elect the claims of Group I
20 (i.e., Claims 1-28), with traverse, and subject to applicants' right to file one or more divisional
21 applications directed to the non-elected inventions.

22 Effect of Amendments:

23 As noted by the Examiner, the claims are currently directed to apparatus claims, method
24 claims directed to making an apparatus, and method claims directed at using an apparatus.
25 Applicants have amended the claims herein to provide more correlation between the claims, in an
26 attempt to enable the different types of claims to be examined together.

27 The apparatus claims encompass a model of a human head that includes a simulated patent
28 suture that can be detected by ultrasound because of the echogenicity of the simulated patent suture.

29 The process claims directed to making a medical model are now specifically directed to
30 making models including a simulated patent suture that can be detected by ultrasound because of the

1 echogenicity of the simulated patent suture.

2 The process claims directed at using a medical model for training are now specifically
3 directed to using a model including a simulated patent suture that can be detected by ultrasound
4 because of the echogenicity of the simulated patent suture.

5 Because the claims are now directed to an apparatus, a method of making the apparatus, and a
6 method of using the apparatus, there does not appear to be an undue burden on the Examiner in
7 examining the claims together.

8 Traversal of the Restriction of Inventions I and III:

9 The Examiner asserts that the Inventions I and III are related as product and process. The
10 Examiner specifically asserts, referring to MPEP 806.05(e), that the apparatus of Invention I can be
11 used to perform other methods, such as teaching medical student to perform head positioning prior
12 to an x-ray procedure, that is not the same as the method of Invention III.

13 MPEP 806.05(e) states: “*Process and apparatus for its practice can be shown to be distinct*
14 *inventions, if either or both of the following can be shown: (A) that the process as claimed can be*
15 *practiced by another materially different apparatus or by hand; or (B) that the apparatus as claimed*
16 *can be used to practice another materially different process.”* (Emphasis added.)

17 Significantly, both the method and apparatus claims (Invention I and III) include the common
18 element of a life sized model of a human head, the model including a plurality of simulated skull
19 sutures disposed at anatomically correct locations (including a simulated patent suture that can be
20 detected by ultrasound because of the echogenicity of the simulated patent suture) . The Examiner is
21 correct that a life sized model of a human head could be used to train medical student to perform
22 correct head positioning prior to an x-ray procedure. However, the Examiner simply cannot ignore
23 the additional structural elements recited in applicants’ apparatus claims. MPEP 806.05(e)
24 specifically requires determining if the apparatus as claimed *can be used to practice another*
25 *materially different process* (emphasis added). The apparatus *as claimed* includes a plurality of
26 simulated skull sutures disposed at anatomically correct locations, including a simulated patent suture
27 that can be detected by ultrasound because of the echogenicity of the simulated patent suture. Such
28 structural elements provide absolutely no benefit with respect to the head positioning procedure
29 identified by the Examiner, but are required to enable the apparatus to be used to implement the
30 claimed method.

1 The "apparatus as claimed" language of MPEP 806.05(e) appears to require the analysis as to
2 whether an apparatus can be used for a different process to be performed such that the proposed
3 additional use is logically related to the invention as claimed. Tools (i.e., apparatus) designed to
4 implement a specific function can sometimes be used for other purposes. A cell phone *can* be used as
5 a paperweight, but that is not a very logical use, because it ignores the functional elements of a cell
6 phone that provide the cell phones communication utility. Clearly, the "apparatus as claimed"
7 language of MPEP 806.05(e) requires that the additional use must be logical in light of *all of the*
8 *structural and functional elements of the apparatus* (i.e., of the apparatus of claimed). In other
9 words, use of the claimed apparatus for a materially different process must be analyzed in light of *all*
10 of the elements in the claimed apparatus.

11 As noted above, the claimed apparatus includes functional structural elements (the simulated
12 skull sutures including a simulated patent suture that can be detected by ultrasound because of the
13 echogenicity of the simulated patent suture) that are completely irrelevant to the additional process
14 identified by the Examiner. As such, restriction based on such a use appears to be inconsistent with
15 MPEP 806.05(e). Applicants respectfully request that either a materially different process be
16 identified that logically relates to the apparatus as claimed (i.e., a use that requires the simulated skull
17 sutures including a simulated patent suture that can be detected by ultrasound because of the
18 echogenicity of the simulated patent suture as present in the apparatus of Invention I), or that the
19 claims encompassed by Groups I and III be examined together.

20 Traverse of the Restriction of Groups I and II:

21 The Examiner asserts that the Groups I and II are related as product made and process of
22 making. The Examiner specifically asserts, referring to MPEP 806.05(f), that the apparatus of
23 Group I can be made by a materially different process, such as molding a model of a human head
24 including the simulated skull sutures.

25 Applicants respectfully submit that there is not a reasonable likelihood of success that the
26 molded model can be used as an ultrasound simulator. The apparatus of Group I must not only
27 include structural elements that visually resemble skull sutures, those simulated sutures must be
28 discernable in an ultrasound image. For example, Claim 1 specifically states that *an echogenicity of*
29 *each simulated patent skull suture enabling the simulated patent skull suture to be readily*
30 *distinguishable in an ultrasound image of said model.*

1 The method of Group II forms openings in a model of a head where patent sutures are to be
2 simulated, because such openings can be identified in an ultrasound image. Claim 29 has been
3 specifically amended to require that the model be made such that it includes a simulated patent
4 suture that can be detected by ultrasound because of the echogenicity of the simulated patent suture.
5 For the patent suture, ultrasound responds differently to the material of the model and the lack of
6 the material of the model (the openings). In the case of the molded model suggested by the
7 Examiner, although the molded sutures could be visually observed, the molded sutures are not
8 likely to be visible in an ultrasound image, because the echogenicity of the molded sutures will be
9 reasonably equivalent to the echogenicity of the rest of the model (because the material of the
10 model has not changed, just its shape/form). Ultrasound responds to significant changes in the
11 density of a material (bone versus tissue, or the material of a skull model and voids/openings in the
12 skull model). Because the molded model suggested by the Examiner would be substantially
13 uniform as to its material composition, the molded sutures will be difficult to discern (the sutures
14 will not have a different echogenicity) using ultrasound, even if the material used to generate the
15 model is a bit thicker or thinner at the suture. Unless the material is changed to achieve a
16 substantially different density (or more explicitly, a different echogenicity) at the simulated patent
17 suture, the echogenicity will not be sufficiently different to enable the patent suture to be visible on
18 an ultrasound scan.

19 Applicants respectfully request that either a materially different process for generating a
20 model having a simulated patent suture that can be detected by ultrasound because of the
21 echogenicity of the simulated patent suture be identified, or that the claims encompassed by Groups I
22 and II be examined together.

23 Traverse of the Restriction of Groups II and III:

24 The Examiner asserts that the Groups II and III are directed to related processes, referring to
25 MPEP 806.05(j). The Examiner specifically asserts that the method of using a medical simulator of
26 Invention III can be performed using a generic medical simulator (i.e., by a product made a process
27 different than that encompassed by Invention II) with a reasonable expectation of success.

28 Applicants respectfully submit that MPEP 806.05(j) specifically states that “*To support a*
29 *requirement for restriction between two or more related product inventions, or between two or more*
30 *related process inventions, both two-way distinctness and reasons for insisting on restriction are*

1 necessary, i.e., separate classification, status in the art, or field of search" (emphasis added). The
2 Examiner has stated that Groups II and III are classified in Class 434, subclass 270. There is no
3 evidence that Groups II and III have separate classification, status in the art, or field of search, thus
4 restriction is improper per MPEP 806.05(j), and the claims of Groups II and III should be examined
5 together.

6 Further, applicants respectfully submit that *there is not a reasonable likelihood of success*
7 that the method of using a medical simulator of Group III can be performed using a generic medical
8 simulator (i.e., by a product made a process different than that encompassed by Group II). The
9 method of Group III requires a medical simulator molded model can be used as an ultrasound
10 simulator, including the step of providing a model that includes a simulated patent suture that can be
11 detected by ultrasound because of the echogenicity of the simulated patent suture. The method of
12 Group II is directed to making a model that includes a simulated patent suture that can be detected by
13 ultrasound because of the echogenicity of the simulated patent suture. There is simply no evidence
14 that a generic medical simulator would include a simulated patent suture that can be detected by
15 ultrasound because of the echogenicity of the simulated patent suture, nor any evidence that a model
16 including a simulated patent suture that can be detected by ultrasound because of the echogenicity of
17 the simulated patent suture could be made by any method other than the method of Group II. Thus,
18 the claims encompassed by Groups II and III should be examined together.

19 In view of the amendment and the Remarks set forth above, it will be apparent that the claims
20 in this application should be examined together, and that the restriction requirement should be
21 withdrawn. Should any further questions remain, the Examiner is invited to telephone applicants'
22 attorney at the number listed below.

23
24 Respectfully submitted,

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